K013660

DEC 0 5 2001

Section F

510k Summary

1. Sponsor Name

RadioMed Corporation
One Industrial Way
Tyngsboro, Massachusetts 01879-1400

Telephone: (978) 649-0300 voice
(978) 649-0333 fax

Contact Individual: Gordon Roberts

2. Device Name

Proprietary Name:	GENETRA™
Common/Usual Name:	Brachytherapy Radionuclide Source
Classification Name:	Brachytherapy Radionuclide

3. Identification of Predicate or Legally Marketed Device

The predicate device for GENETRA™ is the RadioMed™ Source K001070.

4. Device Description

GENETRA™ utilizes Pd-103 as the radionuclide for brachytherapy. GENETRA™ exists in the form of a coiled rhodium wire. The rhodium matrix also provides the radiopacity of the device. GENETRA™ is a naturally sealed source in the form of a wire.

GENETRA™ is packaged non-sterile, single use, and is to be sterilized by the end user in accordance with a validated sterilization process. Sterilization is accomplished by exposure to steam autoclave.

GENETRA™ will be manufactured, labeled and packaged under GMP controls. Upon completion of the manufacturing and assembly process the device will be inspected to assure compliance to specifications. The devices will be tested in accordance with Standard Operating Procedures.

The sources are delivered using a 19 gauge needle and stylet. Currently marketed Brachytherapy seeds are delivered using a 17 or 18 gauge needle and stylet.

5. Intended Use

The intended use and indications for use of the modified device as described in its labeling have not changed.

GENETRA™ with activities from 0.1 to 5.0 mCi per centimeter length is indicated for temporary or permanent interstitial implantation or surface application to treat selected localized tumors. They can be used as either primary treatment or as treatment for residual disease after excision of primary or recurrent tumors. GENETRA may be used concurrently with or following treatment with other interventions, such as external beam therapy, hyperthermia, or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate and other accessible tumors are commonly treated.

6. Comparison of Technological Characteristics

The fundamental scientific technology of the modified device has not changed.

Predicate Device: RadioMed™ Source

510(k) Number: K001070

The design of the predicate RadioMed™ Source is identical to GENETRA™. This is a sealed source in the form of a wire from which to deliver a therapeutic dosage of radioactive energy.

The energy emitted for GENETRA™ and the RadioMed™ Source is identical: 20-23 keV x-rays.

The materials that make up the components of the predicate RadioMed™ Source and GENETRA™ are identical. The packaging has been modified to utilize a glass barrel with the original stainless steel cartridge.
GENETRA™ uses rhodium as did the RadioMed™ Source.
The radionuclide for GENETRA™ is Palladium – 103, which is the same as the radionuclide used for the predicate RadioMed™ Source.

The delivery of the predicate RadioMed™ Source is through a 17 or 18-gauge needle and stylet.

7. Performance Testing

Summary of standards achieved:

FDA QSR 21 CFR Part 820 Good Manufacturing Practices
ISO 10993-1 1992 (E) Biological Evaluation of Medical Devices
ANSI N43.6-1997: Classification of sealed radioactive sources
ANSI N44.1-1973 Integrity and Test Specifications for selected Brachytherapy Sources
ANSI N44.2-1973 Leak testing radioactive brachytherapy sources
ISO 9978: 1992(E) "Radiation protection – Sealed radioactive sources – Leakage test methods".
AAMI Standard 11134-1994 Recommended practice for Steam Autoclave

The "performance" of GENETRA™ is subdivided into four categories

1. Radiation Energy
2. Source Strength Measurement: Calibration and Calibration Accuracy
3. Dose Comparison
4. Sealed Source Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2001

Mr. Gordon Roberts
Quality Assurance and Regulatory
Affairs Manager
RadioMed Corporation
One Industrial Way
Tyngsboro, MA 01879

Re: K013660
Trade/Device Name: GENETRA™
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide
brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: November 2, 2001
Received: November 6, 2001

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

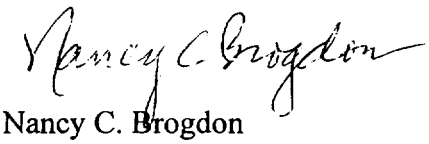
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section E

Indications For Use

GENETRA™ with activities from 0.1 to 5.0 mCi per centimeter length is indicated for temporary or permanent interstitial implantation or surface application to treat selected localized tumors. They can be used either as the primary treatment or as treatment for residual disease after excision of primary or recurrent tumors. GENETRA™ may be used concurrently with or following treatment with other interventions, such as external beam therapy, hyperthermia, or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate and other accessible tumors are commonly treated.

Prescription Use ✓

/Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013660